

AMENDMENT TO THE SPECIFICATION

Please amend the specification by marked up replacement paragraph(s) as follows.

Please replace the paragraph beginning at page 1, line 13, with the following rewritten paragraph:

In the knee replacement and arthroplasty operation, a replacement to knee prosthesis (tibiofemoral (T-F) joint) is done. Known in a prior art is a knee prosthesis, which includes a femoral component made of a metal material and fixed to an osteotomized surface at a femoral distal end, a tibial plate made of a metal material and fixed to an osteotomized surface at a tibial proximal end, and a surface component made of a plastic material such as a polyethylene and arranged between the femoral component and the tibial plate. In such a type of knee prosthesis, it is desired that a flexion and extension of tibiofemoral joint along a wide range of knee flex angle such as 150 degree must be possible. In view of this, the femoral component is smoothly curved such that the femoral component covers the entire osteotomized surface, which extends from [[a]] an anterior part and a posterior part, of the femoral bone. In addition, the surface component made of the polyethylene material on the osteotomized surface at a tibial proximal end is formed such that the surface component has a shape, which is matched to the outer shape of the femoral component along the entire range of the knee motion.

Please replace the paragraph beginning at page 1, line 31, with the following rewritten paragraph:

During the execution of the total knee replacement operation, a precisely mounted condition of all of the components constructing knee joint is essential. In order to obtain such a condition, a possibility of a desired adjustment is essential as to a gap between osteotomized surfaces at a femoral distal end and a tibial proximal end as well as an inclination between these

osteotomized surfaces. In view of this, during the execution of the surgical operation, a measurement of the gap as well as the inclination is done, while applying a tension of a predetermined value in a media and lateral collateral ligaments and in a patellar tendon, and, then, if a desired value of the gap or a desired value of the inclination is not obtained, a suitable relaxation or detachment of the media or lateral collateral ligament (soft tissues) attached to the femoral and tibial bones is done, thereby adjusting the gap or inclination or the both. Such [[an]] a gap and inclination measurement as well as an adjustment of the same are, conventionally, done at both of [[an]] extended and [[a]] flexed conditions of the knee.

Please replace the paragraph beginning at page 2, line 28, with the following rewritten paragraph:

In Ashby et al., both of the tibial and femoral engaging surfaces extend, in a straight manner, anteriorly from the base and the moving head, respectively. Such a straight arrangement prevents the apparatus from being inserted between the femoral and tibial osteotomized surfaces without patellar eversion. Namely, in order to allow the apparatus to be installed, a patella eversion is done laterally from [[an]] a medial skin incision line, thereby generating a space for an installation of the device. Furthermore, the patella eversion is maintained during the entire period for the measurement of the gap as well as the ligament balance.

Please replace the paragraph beginning at page 4, line 4, with the following rewritten paragraph:

According to the first aspect of the present invention, an apparatus in a total knee replacement operation is provided for measuring a joint gap and ligament balance between [[a]]

an osteotomized surface at a femoral distal end and a osteotomized surface at a tibial proximal end, said apparatus comprising:

a base;

a first engaging member on said base for an engagement with said osteotomized surface at the tibial proximal end;

a moving body;

a second engaging member on said moving body for an engagement with said osteotomized surface at said femoral distal end, said second engaging member being rotatable on the moving body about an axis substantially parallel with respect to said osteotomized surface at the femoral distal end;

said base and moving member being connected with each other so that the first and second engaging members are selectively moved between a direction where the first and second engaging members are moved toward each other and a direction where the first and second engaging members are moved away from each other;

a driving member, by which said moving member is moved with respect to the base so that the first and second engaging members are moved in the direction away from each other motor;

an locking member on the moving body, said stopper member engaging with the driving member for locking the movement of the driving member in the direction where the first and second engaging members are moved toward each other;

a first indicator indicating the value corresponding the spacing between the first and second engaging members, and:

a second indicator indicating the value corresponding the angle between the first and second engaging members,

said first and second engaging members being under an offset arrangement with respect to said base and moving body, respectively.

Please replace the paragraph beginning at page 4, line 36, with the following rewritten paragraph:

In the operation of this aspect of the invention, prior to the installation of the apparatus according to the present invention, a patellar eversion is done in a lateral direction from a skin incision location. Then, the first and second engaging members are inserted to a space between osteotomized surfaces at a femoral distal end and a tibial proximal end, in such a manner that the first engaging member is engaged with the osteotomized surface at the tibial proximal end and the second engaging member is engaged with the osteotomized surface at the femoral distal end. Under the condition that the first and the second engaging members are engaged respectively with the osteotomized surfaces at the femoral distal end and the tibial proximal end is obtained, the patellar eversion is cancelled, so that the patellar is returned to a non-everted physiological position. In other words, the offset arrangement of the first and second engaging members with respect, respectively, to the base and the moving body makes it possible to obtain a condition that the base and the main body are located at positions not intervened with the patella. In this condition, the driving member is operated by a tool such as a torque wrench, in such a manner that the spacing between the first and second engaging members is increased against the tension generating in the soft tissues stabilizing the knee tissues. The driving member is locked by a suitable means such as a latchet mechanism when a predetermined force is generated in the driving member. On this locked condition, a reading of the first scale is obtained, which corresponds to the value of the gap between the tibial osteotomized surface and the femoral osteotomized surface. Furthermore, a reading of the second scale is obtained, which corresponds

to an inclination between the tibial osteotomized surface and the femoral osteotomized surface, i.e., degree of imbalance in ligament. A very important advantage of the offset arrangement of the first and second engaging members with respect to the base and the moving body, respectively, according to the present invention is that the gap as well as the imbalance are measured without any substantial patella eversion, i.e., under a intrinsic position of the patella which is directed anteriorly. As a result, a measurement of the gap as well as imbalance becomes possible without any adverse effect, which otherwise would occur when a measurement is done with patella eversion. In other words, according to the present invention, a measurement can be done under an intrinsic condition of the knee from the view point of physiology.

Please replace the paragraph beginning at page 6, line 2, with the following rewritten paragraph:

According to the second aspect of the present invention, an apparatus is provided for use in a total knee replacement operation for measuring a joint gap and ligament balance between an osteotomized surface at a femoral distal end and an osteotomized surface at a tibial proximal end, said apparatus comprising:

- a femoral component for an insertion to the osteotomized surface at a femoral distal end ;

- a base;

- a first engaging member on said base for an engagement with said osteotomized surface at the tibial proximal end;

- a moving body;

- a second engaging member on said moving body for an engagement with said osteotomized surface at said femoral distal end, said second engaging member being for mounting thereon said femoral component, said second engaging member being rotatable on the

moving body about an axis substantially parallel with respect to said osteotomized surface at the femoral distal end;

said base and moving member being connected with each other so that the first and second engaging members are selectively moved between a direction where the first and second engaging members are moved toward each other and a direction where the first and second engaging members are moved away from each other;

a driving member, by which said moving member is moved with respect to the base so that the first and second engaging members are moved in the direction away from each other motor;

an locking member on the moving body, said stopper member engaging with the driving member for locking the movement of the driving member in the direction where the first and second engaging members are moved toward each other;

a first indicator indicating the value corresponding the spacing between the first and second engaging members, and:

a second indicator indicating the value corresponding the inclination between the first and second engaging members.

Please replace the paragraph beginning at page 7, line 32, with the following rewritten paragraph:

Preferably, said second engaging member may have, at its surface remote from the first engaging member, a fitting part, and wherein the device further comprises ~~[[a]]~~ an auxiliary guiding member for a fitted engagement with said fitting part on the second engaging member and engaged with the femoral component. In this preferred construction, the auxiliary guiding member guides the femoral component in such a manner that a smooth movement of the femoral

component with respect to the second engaging member is obtained along a desired range of angle of the femoral bone with respect to the tibial bone. Furthermore, a plurality of the guiding member of different sizes can be prepared respectively for the different sizes of the existing different sizes of femoral components, while the guiding member of different sizes can be inserted to the second engaging member. As a result, a selection of a desired size of a guiding member matched to a particular size of a femoral component matched to the particular patient allows the femoral component to be fitted to the fitting part on the second engaging member. In other words, with respect to the various sizes of the femoral components, the measurement of the gap as well as the ligament balance is realized by one and same measuring apparatus (tensor) so long as a suitable size of the guiding member matched to the femoral component inserted to the patient is selected.

Please replace the paragraph beginning at page 13, line 18, with the following rewritten paragraph:

As shown in Fig. 5, the auxiliary guiding piece 50 is adapted to be mounted to the raised portion or projection 48 on the supporting plate 22. Namely, the auxiliary guiding piece 50 has a rounded front surface 50A, a rear flat end surface 50B, and a slot 53 of an elongated rectangular cross-sectional shape, which extends completely through the auxiliary guiding piece 50. This slot 53 has a dimension, which allows the raised portion 48 to be smoothly inserted and to be neatly fitted, resulting in a stable mounted condition of the auxiliary guiding piece 50 on the supporting plate 22. In addition, the auxiliary guiding piece 50 is provided with a closed-end cavity 55 opening laterally to the inner wall of the slot 53. A spherical member 56 is stored in the closed-end cavity 55 and a spring 58 is provided for urging the spherical member in such a manner that the spherical member 56 is partly protruded to the slot 53. However, an opening portion of the

closed-end cavity 55 is somewhat narrowed to prevent the spherical member 56 from being dropped out of the slot 53. During the mounting of the auxiliary guiding piece 50 to the raised portion 48 on the supporting plate 22 along an arrow g in Fig. 4, the spherical member 56 is, first, contacted with the raised portion 48, which causes the spherical member 56 to be pushed inwardly and moved toward the bottom of the closed-end cavity 55 against the force of the spring 58. The raised portion (projection) 48 is one piece member of the boss portion 22-1 of the supporting plate 22 and extends upwardly from the foundation portion 48-1 as shown in Fig. 8. Furthermore, ~~[[The]]~~ the raised portion 48 has a slightly narrowed width over that of the foundation portion 48-1, as shown in Fig. 1. The insertion of the auxiliary guiding piece 50 to the projected portion 48 via the slot 53 causes, finally, the piece 50 to be engaged with the foundation portion 48-1 under a face-to-face contact relationship, thereby obtaining a stabled fixed condition of the ~~[[the]]~~ auxiliary guiding piece 50 on the supporting plate 22. Further, as shown in Fig. 4, formed on the rear surface of the raised portion 48 is a recess 48A, with which the spherical member 56 is engaged under a spring force by the spring 58. In other words, a snap engagement of the auxiliary guiding piece 50 with respect to the projected portion 48 is obtained, resulting in a firmly fixed condition of the auxiliary guiding piece 50 on the projected portion 48. This does not cause the piece 50 to be difficult in its removal. Namely, upon an upward movement of the piece 50 in the direction opposite to the arrow g in Fig. 4, the spherical member 56 is moved inwardly against the force of the spring 58 in the slot 55 under the cam like action of the recess 48A with respect to the spherical member 56, thereby allowing the auxiliary guiding piece 50 to be easily detached from the projected portion 48, i.e., the supporting plate 22.

Please replace the paragraph beginning at page 16, line 17, with the following rewritten paragraph¹:

As shown in Fig. 7, the femoral bone F is osteotomized by an end surface FA, a posterior surface FB, ~~[[a]]~~ an anterior surface FC and a slant surface FD that runs from the end surface FA to the anterior surface FC, at its distal end. On the other hand, the tibial bone T is osteotomized flatly by an end surface TA at its proximal end. And then, a trial femoral component having all the same sizes as that of the femoral component to be fitted to the patient is prepared to fit to the femoral bone F of the patient such that an opposed and contacted arrangement is obtained between the surfaces 52A and FA, 52B and FB, 52C and FC, and 52D and FD. As described before with reference to Fig. 9, the patella P is outwardly everted from a skin incision line 76 as shown by P', and the gap between opposing faces of the femoral bone F and the tibial bone T is in an outwardly opened state, where the measuring apparatus of the present invention is installed. As shown in Figs. 7 and 9, the engaging plate 14 extending from the base 10 via the arm 12 is introduced into the gap between opposing osteotomized surfaces of the femoral bone F and the tibial bone T, and is fixed to the upper surface TA of the tibial bone T by driving the fixing nails 16 downwardly built in the bottom surface of the engaging plate 14. On the other hand, the supporting plate 22 at the end of the arm 20 extending from the moving body 18 is also introduced into the gap between opposing osteotomized surfaces of the femoral bone F and the tibial bone T in the same way as in the above. Thereupon, the raised portion 48 on the supporting plate 22 is fitted with the auxiliary guiding piece 50 matched to the particular femoral component 52 for trial use for a patient. Then, the supporting plate 22 is introduced so

¹ Please note that the underlines provided to the capital letters in this paragraph as follows are in the original specification, but are not added by the present Amendment: F in the lines 17 and 23 on page 16, P in the line 26 on page 16, F in the line 28 on page 16, T in the line 29 on page 16, F in the line 32 on page 16, T in the lines 33 and 34 on page 16, F in the line 9 on page 17, T in the line 10 on page 17, P in the line 13 on page 17, and Q in the line 24 on page 17.

that the auxiliary guiding piece 50 is positioned in the guiding channel 54 of the trial femoral component 52. After the insertion of the engaging plate 14 and the supporting plate 22 into the gap between opposing osteotomized surfaces of the femoral bone F and the tibial bone T as the above explained, the patella eversion as shown by the phantom line P' in Fig. 9 is cancelled, i.e., the patella is returned to its original position facing ahead as shown by the phantom line P in Fig. 9. In the present invention, the engaging plate 14 and the supporting plate 22 are under an offset relationship with respect to the base 10 and the moving body 18, respectively (refer to Fig. 6 for the offset relationship). That is, as shown in Fig. 9, the base 10 and the moving body 18 are positioned inside of the knee under the condition that the engaging plate 14 and the supporting plate 22 are fitted or inserted to the tibial bone and the femoral bone, respectively. What makes the patella eversion to be unnecessary during the measurement of the joint gap and the ligament balance according to the present invention is this offset arrangement. Namely, the members 10 and 18 do not prevent the patella to be returned to a position directed ~~an-te-ri-orly~~ anteriorly as shown by the phantom line Q. Thus, it becomes to be possible to carry out the measurement under the original physiological state of the knee without any eversion of the patella P.

Please replace the paragraph beginning at page 20, line 27, with the following rewritten paragraph:

Although the present invention has been described with reference to an embodiment, it will be clear that many modifications and changes may be made by those skilled in this art without departing scopes and ~~sprits~~ spirits of the present invention.